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PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,298	SHARPE ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/21/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 21-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 21-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9 and 21-37 are pending. Applicants previously cancelled claims 10-20. Applicants have amended claims 1, 21, and 30. Receipt and consideration of Applicants' amended claim set and arguments/remarks filed on December 21, 2007 are acknowledged. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments. Applicants' claim amendments have necessitated new grounds of rejection (e.g. 112, 1st).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 21-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter). The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' specification does not provide support for the range of surfactant of "***about*** 0.002 to ***about*** 0.01%" for any surfactant. The only support for a specific amount of any surfactant is disclosed on page 12, in Table 2 of Example 2 of Applicants' specification, which is limited to compositions wherein the surfactant is lecithin and only supports a range of from 0.002% w/w to 0.01% w/w.

The remaining claims are rejected for depending upon a rejected claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 21-29 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained** for the reasons of record set forth in the office action mailed on January 30, 2007, which has been restated below for Applicants' convenience.

Claim 21 is vague and indefinite because it requires that the composition within the claimed metered dose inhaler (MDI) be free of a bulking agent. Applicants have defined the term "bulking agent" on pages 6-7 of the specification (i.e. paragraph [0010]) to mean, "***an inert substance in which or onto which the active drug ingredient(s) and excipients, if present, are dispersed***." This definition is inclusive of the propellant, HFA 227, in the composition within the claimed MDI, because HFA 227 is an inert substance and the active ingredients are clearly dispersed (i.e. suspended) in HFA 227, as evidenced by the language of claim 21 that the composition is a suspension formulation. Suspensions are dispersions. It is immaterial that Applicants have not made direct reference to HFA 227 as a bulking agent.

The remaining claims are rejected for depending from a rejected claim.

Response to Arguments

Applicant's arguments filed December 21, 2007 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection based on their assertions (1) that according to established case law (i.e. Phillips v. AWH Corp., 415 Fed. 3d 1303 Fed. Cir. 2005,

cert denied 2006 US Lexus 1154 (Feb. 21, 2006)) the claims must be read in light of the specification; (2) the specification allegedly distinguishes "bulking agents" from propellants; and (3) that the term "bulking agent" is clearly defined in Applicants' specification.

Regarding (1) and (3), the Examiner agrees that bulking agent has a clear definition and that case law supports reading the claims in light of the specification. The Examiner has properly applied Applicants' clear definition of a bulking agent as indicated by the courts as being proper. Namely a bulking agent has been treated as being any substance in which or onto which active drug ingredient(s) and excipient(s), if present are dispersed. Applicants are claiming an aerosol suspension comprising mometasone furoate, dry powder surfactant, and HFA 227. The specification clearly suggests that the active ingredient, mometasone furoate is insoluble in HFA 227 (see page 3, lines 5-11 of the instant specification) and the claims clearly indicate that the surfactant is insoluble (i.e. a the surfactant would not be in the form of a dry powder if it were soluble in HFA 227). Thus, the HFA 227 propellant is clearly a substance in which or onto which active drug ingredient (i.e. mometasone furoate) and excipient (i.e. dry powder surfactant) is dispersed, and thus, HFA 227 is a bulking agent as defined by Applicants. The Examiner respectfully disagrees with Applicants' argument (2) for the reasons above and the reasons already of record. It is immaterial whether Applicants have identified HFA 227 as also being a propellant, because Applicants' definition clearly encompasses HFA 227 and does not exclude propellants from the definition of a bulking agent.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 6-9, 21, 26, 28-30, and 36-37 under 35 U.S.C. 102(b) as being anticipated by Fassberg (U.S. Patent No. 5,474,759) **is maintained** for the reasons of record, which have been restated below for Applicants' convenience.

Applicants claim a metered dose inhaler containing an aerosol suspension formulation consisting of an effective amount of mometasone furoate, a dry powder surfactant, and HFA 227, wherein the surfactant is presenting an amount of about 0.002 to about 0.01% by weight.

Fassberg discloses suspension aerosol formulations in, for example, Example XIX (col. 8, lines 36-40) consisting of **98.8% w/w HFC 227, 0.1% w/w mometasone furoate, 0.1 % w/w PLURONIC® L 121, and 1.0% MIGLYOL® 812 (i.e. surfactant)**. Other similar formulations are disclosed in Examples XX-XXIII (col. 8, lines 41-56) and claims 1-6 and 8-13. Specifically, claim 10 discloses formulations comprising **0.01-1% w/w mometasone furoate, 25-99.99% HFC 227 (i.e. 1,1,1,2,3,3,3-heptafluoropropane), 0-75% excipient, and 0-3% surfactant**. Fassberg describes the invented formulations as being directed to compositions that are substantially free of CFC's and are particularly **useful in metered dose-pressurized inhalators** (i.e. MDIs) (col. 1, lines 15-20). The suspensions are made by preferably **pressure filling or cold filling procedures into aerosol containers** (e.g. MDIs) (col. 6, line 66 through col. 7, line 3). It is the Examiner's position that the formulations disclosed by Fassberg are inherently contained within a metered dose inhaler in view of Fassberg's complete disclosure, because it is known that aerosol containers include MDIs. It is impossible for one to formulate

pharmaceutical compositions comprising HFC's without using pressurized containers, because under ambient temperature (i.e. ~25 degrees C) and pressure (i.e. ~1 atmosphere) HFC's are gases, whereas in pressurized containers HFC's a liquids. Regarding claims 8-9 and 36-37, it is the Examiner's position that the emitted efficiency and particle size is inherent to the formulations disclosed by Fassberg upon actuation from any MDI. As noted above, claims 8-9 and 36-37 are indefinite as to what aspect of the claimed invention (i.e. the MDI, composition, or both) are responsible for yielding the claimed percent emitted particles and particle size. It is also noted that Fassberg discloses that the particles of the disclosed formulation have a particle size of 1-5 microns (col. 6, lines 25-26) and the value of "about 4.7 microns" reads on a value of 5 microns. Regarding the Markush group of surfactants (e.g. claim 6), Fassberg discloses that soya lecithin is a preferred surfactant (col. 3, lines 40-46). Applicants are reminded that exemplified embodiments are not limiting with regards to the disclosures of a reference. Regarding the limitation that surfactant be present in an amount ranging from about 0.002 to about 0.01%, in Example XXIII (col. 8, lines 53-56), for example, Fassberg exemplifies a composition consisting of **0.1% w/w mometasone furoate, 0.01% w/w TWEEN 20 (i.e. a surfactant), and 99.89% w/w of HFC 227 (i.e. HFA 227)**.

Response to Arguments

Applicant's arguments filed December 21 2007 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection as being improper because (1) the Examiner has not given patentable weight to the phrase "free of a carrier" and (2) Applicants submit that the claims are patentable over the cited references.

Regarding (1), in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "free of a carrier") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). ***None of Applicants' instant claims*** recites the limitation reading "free of a carrier." If Applicants intended to argue the limitation, "free of a bulking agent", this argument is unpersuasive for several reasons.

Firstly, as has been restated above and repeatedly demonstrated clearly on the record, Applicants' definition of a bulking agent as found in Applicants' specification clearly reads on the propellant, HFA 227, being a bulking agent. Secondly, the only claims reciting the limitation, "free of a bulking agent" are claims 21-29, thus it is unclear how this argument could reasonably be used to demonstrate the patentability of claims 1-9 and 30—37. Thirdly, even if the limitation of claims 21-29 reciting that the claimed compositions are "free of a bulking agent" were given patentable weight, Applicants have failed to demonstrate that the prior art compositions contain a bulking agent.

Regarding (2) Applicants have failed to demonstrate that the cited prior do not teach the claimed inventions. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Claims 21-26, 28-29, 31-34, and 36-37 **remain rejected** under 35 U.S.C. 102(b) as being anticipated by Berry et al. (U.S. Patent No. 6,068,832) for the reasons of record, which have been restated below for Applicants' convenience.

Applicants claim a metered dose inhaler **containing** an aerosol suspension formulation consisting of an effective amount of mometasone furoate, a dry powder surfactant, and HFA 227.

Berry discloses formulations comprising **HFC 227 (i.e. HFA 227) (94.969-97.457 % w/w), mometasone furoate (0.032-0.308 % w/w), oleic acid (0.011-0.012 % w/w),** and ethanol (2.492-4.985 % w/w) (col. 5, line 45 through col. 6, line 39; claims 1, 4-7, 15-16), wherein the composition may be contained in a metered dose container **delivering a measured amount of about 10 to about 500 micrograms of mometasone furoate** from a single actuating operation. Oleic acid is inherently a dry powder surfactant, because it is the unsaturated analog of stearic acid, which Applicants explicitly claim as an example of a dry powder surfactant in claim 26.

Regarding the properties of the claimed compositions recited in claims 28-29 and 36-37, these are inherent to the compositions disclosed by Berry, because the compositions are the same. The word "containing" is treated as open claim language equivalent to "comprising."

Response to Arguments

Applicant's arguments filed December 21 2007 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection as being improper for the same reasons rebutted above in the previous maintained rejection under 35 USC 102(b). The Office's

rebuttal of Applicants' arguments is herein incorporated by reference. Furthermore, it is noted Applicants have not presented any specific arguments concerning the alleged deficiencies of the cited Berry reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-9 and 21-37 under 35 U.S.C. 103(a) as being unpatentable over Fassberg et al. (U.S. Patent No. 5,474,759) **is maintained** for the reasons of record as stated above in the instant office action.

Response to Arguments

Applicant's arguments filed December 21 2007 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection as being improper for the same reasons rebutted above in the previous maintained rejection under 35 USC 102(b). The Office's rebuttal of Applicants' arguments is herein incorporated by reference. Furthermore, it is noted Applicants have not presented any specific arguments concerning the alleged deficiencies of the cited Berry reference.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1-5, and 7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,474,759 **is**

maintained, for the reasons of record on pages 11-12 of the office action mailed on October 26, 2005, which have been restated below for Applicants' convenience.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in the scope of the aerosol formulations contained within the MDIs of the instant invention and the dependent claims have the same or obvious similar limitations. Independent claim 1 of the instant application is drawn to metered dose inhalers containing a composition **comprising** an aerosol suspension formulation **comprising** mometasone furoate, a surfactant, and HFA 227, also known as 1,1,1,2,3,3,3-heptafluoropropane. No weight is given to the limitation of claim 1 that the aerosol formulation is free of a carrier. Independent claims 1, 8, and 9 of U.S. Patent No. 5,474,759 (U.S.P.N. '759) are drawn o aerosol formulations consisting essentially of a medicament, including **mometasone furoate** (claims 8 and 9), **HFA 227**, optionally excipients and/or **surfactants**. Mometasone furoate is a medicament. It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to place an aerosol formulation within a metered dose inhaler (MDI), because it is well known in the art to administer aerosol formulations using inhalers, especially MDIs. Therefore, a skilled artisan would have been motivated to make said MDIs containing the aerosol formulations of U.S.P.N. '759 and would have had a reasonable expectation of successfully obtaining MDIs containing said formulations. Regarding the limitations of claims 2-5 and 14-17 of the instant application, these are met by claims 4-7 of U.S.P.N. '759. Claims 14-17 are based upon the product by process of claim 13 and are treated as a product because the process does not impart any structural limitations to said product. The products of claims 13-17 comprise a MDI containing an aerosol formulation comprising

mometasone furoate, a surfactant, and HFA 227. Regarding the new limitations specifying the amount of surfactant present in said claims, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

The provisional rejection on the ground of nonstatutory obviousness-type double patenting of claims 1-9 as being unpatentable over claims 1-9 and 20-26 of copending Application No. 11/071,078 (copending '078) in view of García-Marcos et al. **is maintained** for the reasons of record set forth on pages 4-5 of the office action mailed on June 29, 2006 which have been restated below for Applicants' convenience.

Both the claims of the instant application and copending '078 claim suspension formulations comprising HFA 227 (1,1,1,2,3,3,3-heptafluoropropane) and mometasone furoate as the active agent, as well as metered dose inhalers containing said formulation, and processes of making said suspension aerosol formulations. The difference between the instant application and copending '078 is that copending '078 recites compositions also compromising formoterol fumarate. This deficiency is cured by the teachings of García-Marcos. García-Marcos teaches that the combination of an anti-inflammatory steroid (e.g. mometasone furoate or budesonide) with a long-acting bronchodilator, such as formoterol furoate is known (see pages 26-28). Furoate is a known ester derivative of formoterol. Because the combination of an anti-

inflammatory steroid with a bronchodilator is known, the cited claims of the instant application are *prima facie* obvious over the cited claims of copending '078.

This is a provisional obviousness-type double patenting rejection.

Claims 21-26, 28-29, 31-34, and 36-37 **remain rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-16 of U.S. Patent No. 6,068,832 (USPN '832) for the reasons of record, which have been restated herein for Applicants' convenience.

Although the conflicting claims are not identical, they are not patentably distinct from each other because these are substantially similar and/or mutually obvious. Applicants' claims have been described above. Independent claim 15 of USPN '832 claims a metered dose inhaler comprising an aerosol suspension comprising 1,1,12,3,3,3-heptafluoropropane (i.e. HFA 227), about 1 to about 10 % w/w ethanol, micronized mometasone furoate, and optionally a surfactant. Applicants' claims utilize open claim language, thus the inclusion of ethanol in the claims of USPN '832 is not a distinguishing feature and merely represents an obvious variation of the compositions claimed by Applicants. Therefore, the Examiner concludes that a person of ordinary skill in the art would have found that claims 21-26, 28-29, 31-34, and 36-37 are *prima facie* obvious over claims 15-16 of U.S. Patent No. 6,068,832 (USPN '832).

NOTE: (1) **Applicants have submitted NO arguments** as to why the above rejections on the ground of nonstatutory obviousness-type double patenting are allegedly inappropriate or incorrect. The mere statement of Applicants' belief that the claims are allowable is not a

persuasive argument. Therefore the Examiner concludes that above obviousness-type double patenting rejections (provisional and non-provisional) remain proper. (2) The provisional rejections on the ground of nonstatutory obviousness-type double patenting over copending applications (a) 10/967,719 and (b) 10/649,398 **are moot**, because said copending applications have been abandoned.

Claims 21-25 and 30-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-20, 22-23, and 29 of copending Application No. 11/948,688 ("copending '688", which was filed by Applicants on 11/30/07, approximately 5 months *after* receiving the previous office action mailed on June 27, 2007).

Independent claim 21 of the instant application claims a metered dose inhaler (MDI) containing an aerosol suspension composition comprising (i) an effective amount of mometasone furoate, (b) a dry powder surfactant, and (c) HFA 227, wherein the surfactant is present in an amount from about 0.002 to about 0.01%. Dependent claim 19 of copending '688 claims a MDI produced by a process that deposits a composition comprising (a) at least one drug and (b) HFA 227. Dependent claim 20 of copending '688 indicates that the MDI composition further comprises at least one excipient selected from a group consisting of cosolvents, surfactants, and propellants. Dependent claim 21 of copending '688 specifies that the drug is selected from at least one of mometasone furoate and formoterol fumarate. Dependent claim 29 of copending '688 claims a MDI produced by a process that deposits a composition comprising (a) mometasone furoate anhydrous, (b) formoterol fumarate, (c) surfactant, and (d) HFA 227. The difference between the cited claims of the instant application and copending '688 is that

copending '688 does not recite that the compositions contained in the claimed MDI are free of a bulking agent or have specific amounts of surfactant or drug. This deficiency is prima facie obvious, because aside from the propellant, which reads on a bulking agent per Applicants' specification definition, the claims of copending '688 contain no additional bulking agent. Regarding the amount of surfactant and/or drug present in said claims, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Therefore, claims 21-25 and 30-34 would have been found prima facie obvious over claims 19-20, 22-23, and 29 of copending application 11/948,688.

This is a provisional obviousness-type double patenting rejection.

Claims 21-25 and 30-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-14 and 24-26 of copending Application No. 11/940,046 ("copending '046", which was filed by Applicants on 11/14/07, approximately 5 months *after* receiving the previous office action mailed on June 27, 2007).

Independent claim 21 of the instant application has been described above in the instant office action. Independent claim 13 of copending '046 claims a MDI containing a suspension aerosol composition comprising (a) an effective amount of a compound selected from a group of

4 compounds, including mometasone furoate, mometasone furoate monohydrate, and combinations thereof, (b) HFA 227, and (c) ethanol, wherein the formulation contains less than 500 micrograms of non-volatile residue. Independent claim 24 of copending '046 claims a MDI as described in claim 13 of copending '046, wherein the valve of the MDI comprises less than about 100 micrograms of lubricant. The differences between the cited claims of the instant application and copending '046 is that copending '046 does not recite that the compositions contained in the claimed MDI are free of a bulking agent, have specific amounts of surfactant, and the claims of the instant application are silent as to the amounts of non-volatile residue in the MDI formulation, as well as to the amount of lubricant in the valve of the MDI. These deficiencies are prima facie obvious, because aside from the propellant, which reads on a bulking agent per Applicants' specification definition, the claims of copending '688 contain no additional bulking agent. Regarding the amount of non-volatile residue, the claims of the instant application do not recite the presence of any non-volatile residue and the limitation recited in copending '688 reads a zero amount of non-volatile residue. Regarding the amount of surfactant and/or drug present in said claims, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Therefore,

claims 21-25 and 30-34 would have been found prima facie obvious over claims 13-14 and 24-26 of copending application 11/940,046.

This is a provisional obviousness-type double patenting rejection.

Conclusion

Claims 1-9 and 21-37 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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